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Nicholas deBeer

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LEVINE BAGADE HAN LLP
2483 EAST BAYSHORE ROAD, SUITE 100
PALO ALTO, CA 94303

EXAMINER

SWEET, THOMAS

ART UNIT

PAPER NUMBER

3738

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/621,730	Applicant(s) DEBEER, NICHOLAS	
	Examiner Thomas J. Sweet	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-43 and 50-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-43 and 50-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 02/28/2007 have been fully considered but they are not persuasive. Both the Bao et al and Porter et al references inherently include side(s) (i.e. one of the surfaces forming the outside of or bounding a thing) of different permeability (such as non-permeability or an opening) where the body is filled (36 and 14 respectively). The new claims are rejected below. The Examiners notice that it is well known in the art of surgical balloons use (ePTFE) or (PET) was not addressed so it is now considered admitted prior art.

Claim Objections

Claims are objected to because of the following informalities:

Claim 59 recites the limitation "the first side...the second side" in line 9. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 62 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 62 is not dependent on claim 60 or 61 so the wire is not in the porous body such that it could be removed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 34-37 and 39-43 rejected under 35 U.S.C. 102(e) as being anticipated by Bao et al. (US Pgpub 2003/0220649). Bao et al. disclosed a method of providing an encapsulation device to a desired location (fig. 5), the method comprising; expanding a porous (16 and/or [0073]) body (as shown in fig. 5) to conform to a shape of a target (70) by introducing a first fluid (gas or fluid [0080] such as saline [0229]) into an opening in the body (70), where the porous body has a first side having a permeability different than a remainder of the porous body (at 36 is a side of different permeability); introducing a second fluid into the porous body (curable biomaterial/adhesive [0189]) to displace the first fluid through the porous body ([0073] and/or [0189]); and allowing the second fluid to cure to secure the porous body to the target.

With regard to claims 35-37, the step of inserting a wire reinforcement into the porous body [0061], securing the wire reinforcement to the interior of the porous body [0061], and removing the wire reinforcement from the porous body [0061].

With regard to claim 43, the second fluid is more viscous than the first fluid (inherent since the first fluid displaces the second).

With regard to claims 50 and 51, the porous body further comprises a second side being less permeable than the first side (depending on your point of view, the first side 14 can be more permeable in that fluid flows through 14 or another point of view is 14 is the second less permeable side through which no fluid flows out of the porous body since 17 seals).

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Claims 34-37 and 39-43 are rejected under 35 U.S.C. 102(a) as being anticipated by Porter et al. (US 6,547,804). Porter et al. discloses a method of providing an encapsulation device to a desired location (figs. 1a-6), the method comprising; expanding a porous body (fig. 2) to conform (to be or become similar in form or character) to a shape of a target (an aneurysm) by introducing a first fluid (saline, 30) into an opening in the body (25), where the porous body has a first side having a permeability different than a remainder of the porous body (at 14 is a side of different permeability); introducing a second fluid (32, solidifying/adhesive) into the porous body to displace the first fluid through the porous body (col 4-5, lines 32-5); and allowing the second fluid to cure to secure the porous body to the target.

With regard to claims 35-37, the step of inserting a wire reinforcement into the porous body, securing the wire reinforcement to the interior of the porous body, and removing the wire reinforcement from the porous body (col 3-4, lines 42-15).

With regard to claim 43, the second fluid is more viscous than the first fluid (inherent since the first fluid displaces the second).

With regard to claims 50 and 51, the porous body further comprises a second side being less permeable than the first side (depending on your point of view, the first side 36 can be more permeable in that fluid flows through 36 or another point of view is 36 is the second non-permeable side through which no fluid flows out of the porous body).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al. Bao et al discloses a method as discussed above including the use of polyethylene for the body material. However, Bao et al remains silent as to specifically using (ePTFE) or (PET). It is admitted prior art that surgical balloons use (ePTFE) or (PET) for the purpose of providing a biocompatible balloon material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute (ePTFE) or (PET) for the balloon material of Bao et al since they are biocompatible and such a modification amounts to mere substitution of one functionally equivalent balloon material for another within the art of surgical balloons.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Porter et al. Porter et al discloses a method as discussed above. However, Porter et al remains silent as to specifically using (ePTFE) or (PET). It is admitted prior art that surgical balloons use (ePTFE) or (PET) for the purpose of providing a biocompatible balloon material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute (ePTFE) or (PET) for the balloon material of Porter et al since they are biocompatible and such a modification amounts to mere substitution of one functionally equivalent balloon material for another within the art of surgical balloons.

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Claims 52-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter et al in view of Soltesz et al (US 6527761). Porter et al discloses a method of providing an encapsulation device to a desired location, the method comprising:

expanding a porous body to conform to a shape of a target by introducing a first fluid into an opening in the body;

introducing a second fluid into the porous body to displace the first fluid through the porous body; and

allowing the second fluid to cure to secure the porous body to the target such that the wire reinforcement remains within the porous body (discussed above).

However, Porter et al does not disclose securing a wire reinforcement to an interior surface of the body to assist the body in maintaining the shape. Soltesz et al discloses another encapsulation device (title) including a wire reinforcement (col 3, lines 16-19) to an interior surface of the body (col 3, lines 25-27) for the purpose of assist the body in maintaining the shape (col 3, lines 27-29). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a wire reinforcement as taught by Soltesz et al in the body of Porter et al in order to assist the body in maintaining the shape.

With regard to claim 53, Porter et al remains silent as to specifically using (ePTFE) or (PET). It is admitted prior art that surgical balloons use (ePTFE) or (PET) for the purpose of providing a biocompatible balloon material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute (ePTFE) or (PET) for the balloon material of Porter et al since they are biocompatible and such a modification amounts to mere

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substitution of one functionally equivalent balloon material for another within the art of surgical balloons.

Claims 34-51, 59-61 and 63-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chobotov (US 6395019) in view of Porter et al. Chobotov discloses a method of providing an encapsulation device (fig. 4) to a desired location, the method comprising:

expanding a body (fig. 4) to conform to a shape of a target (vessel) by introducing a first fluid into an opening in the body (33) where the body comprises at least one rib (55) on an exterior surface of the body (fig. 4) and having a larger diameter than the body when expanded (as shown), where expanding the body to conform to the shape mechanically locks the rib against the target (vessel).

However, Chobotov does not disclose the body as porous and introducing a second fluid into the porous body to displace the first fluid through the at least the first side of the porous body differently than the second side of the porous body; and allowing the second fluid to cure to secure the porous body to the target.

Porter et al teaches another encapsulation device including an inflatable porous body and introducing a second fluid into the porous body to displace the first fluid through the at least a first side of the porous body and allowing the second fluid to cure for the purpose secure the porous body to the target. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the inflatable porous material of Porter et al for the inflatable portions (55) of the body of Chobotov and utilizing a second curing fluid in order to secure the body to the target (in order not to destroy the Chobotov reference only the inflatable

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portions, 55 are substituted so that Chobotov would still function as a graft) and as such the second side (inner lumen) of the porous body (fig. 4) would not be permeable.

With regard to claim 60, further comprising the step of inserting a wire reinforcement (66) into the porous body (fig. 4).

With regard to claim 61, further comprising the step of securing the wire reinforcement (66) to the interior of the porous body (such as shown in fig. 3) .

With regard to claim 63, Porter et al remains silent as to specifically using (ePTFE) or (PET). It is admitted prior art that surgical balloons use (ePTFE) or (PET) for the purpose of providing a biocompatible balloon material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute (ePTFE) or (PET) for the balloon material of Porter et al since they are biocompatible and such a modification amounts to mere substitution of one functionally equivalent balloon material for another within the art of surgical balloons.

With regard to claims 66-68, porter et al discloses these limitations as discussed above.

Claims 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chobotov in view of Porter et al as applied to claim 59 above, and further in view of Aboul-Hosn (US 6,976,996). Chobotov as modified discloses a method of providing an encapsulation device (as discussed above). Chobotov as modified does not discloses the step of removing the wire reinforcement from the porous body. Chobotov does disclose using a balloon catheter to removably reinforce the body during deployment (col 5, lines 51-59). It is well known in the art of balloon catheters to including reinforcing wire for the purpose of preventing kinks as

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demonstrated by Aboul-Hosn (fig. 20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wire reinforcement in the catheter or substitute the balloon catheter of Aboul-Hosn for the balloon catheter of Chobotov in order to prevent kinks. Such a modification would include a step of inserting a wire reinforcement (in the reinforcing balloon) into the porous body (fig. 4), securing the wire to the body by via the balloon and removing a wire reinforcement once the body is deployed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 5:45am - 4:15pm, Tu-Th.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet
Examiner AU 3738

A handwritten signature in black ink, appearing to read 'Thomas J Sweet', written over the printed name and title.